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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,008	03/05/2002	Alexander Kamyshny	1268-154	4395
22429	7590	01/15/2004	EXAMINER ALEXANDER, LYLE	
LOWE HAUPTMAN GILMAN AND BERNER, LLP 1700 DIAGONAL ROAD SUITE 300/310 ALEXANDRIA, VA 22314			ART UNIT 1743	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,008

Applicant(s)

KAMYSHNY ET AL. 

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 052802.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-12, 16-24, 26, 28-30, 32-33, 39-43, 45 and 47-48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Michael (USP 5,468,450).

Michael teaches diagnostics beads for indication of occult blood in animal litter. Column 2 lines 1+ teach the beads can be made of cellulose. Column 2 lines 46-60 teach the beads may have a diameter between 1 to 40 mm and may comprise from 1-100% of the litter. Column 4 lines 40+ teach TMB as the indicator, polyvinyl pyrrolidone(PVP) as the binder and cumene hydroperoxide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13,31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael.

See Michael *supra*.

Michael is silent to calcium carbonate and alumina as organic filler, application of the composition as a spray or as a dry powder.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results.

The choice of well known inert materials, such as calcium carbonate or alumina, are result effective variables with the known and expected result of creating a non-reactive substrate upon which the reagent is placed. Additionally, calcium carbonate and alumina are readily available and inexpensive. It would have been within the skill

of the art to modify Michael to use calcium carbonate or alumina as a filler material as optimization of a result effective variable and to gain the above advantages.

The method of application of an indicator to a substrate is a result effective variable having the expected result of placement of the indicator in the desired location. Spraying the indicator has the advantages of very precise placement capable of using very small volumes of indicator that is cost saving. Application of dry indicator is advantageous because it does not require sophisticated equipment and can be done by the layperson on site. It would have been within the skill of the art to modify Michael and apply the reagent by either spraying or as a dry powder as optimization of a result effective variable and to gain the above advantages.

Claims 6,14-15, 25, 37-38, 44 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael in view of Puglia (USP 5,318,894).

See Michael supra.

Michael is silent to use of 6-methoxyquinoline and metal sequestering agents.

Puglia teaches a composition and device for the detection of occult blood using a TMB indicator system. Puglia teaches in column 23 lines 48+ use of 6-methoxyquinoline as a promoter to achieve a more sensitive assay. Further, in column 8 and 12 lines 9-26 and 1-20 respectively teach it is advantageous to use chelated ferric ion complexes to eliminate interfering compounds having peroxidatively activity that could give false positive results. The claimed additive and metal sequestrant have been read on the chelated ferric ion complex.

It would have been within the skill of the art to modify Michael in view of Puglia and use 6-methoxyquinoline and a chelated ferric ion complexes to gain the above advantages.

Allowable Subject Matter

Claims 8,27 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The art recognizes ascorbic acid as interfering with detection of occult blood when using TMB as the reagent (as an example see Puglia USP 5,318,894 column 5 lines 37+, col. 13 lines 55+, etc.). It would not have been obvious to use a ascorbic acid, which is recognized as interfering with occult blood detection with a TMB indicator, as a stabilizer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Lyle A Alexander
Primary Examiner
Art Unit 1743

